

## **Proposed Amendments**

**105 CMR 660 .000**

PM3001373936

**105 CMR: Department of Public Health****105 CMR 660.000 Cigarette and Smokeless Tobacco Products: Reports of Nicotine Ratings****660.001: Purpose****660.002: Authority****660.003: Definitions****660.100: General Requirements for Annual Reports****660.101: Cigarette Nicotine Yield Reporting Requirements: Product Design Characteristics****660.102: Additional Cigarette Nicotine Yield Reporting Requirements, Selection and Testing of Brands****660.103: Cigarette Nicotine Yield Reporting Requirements for All Other Brands****660.104: Cigarette Free Nicotine Reporting Requirements****660.105: Human Intake of Nicotine Reporting Requirements****660.106: Smokeless Tobacco Products: Reporting Requirements****660.200: Testing Methods****660.300: Characterization of Cigarette Reporting Form****660.400: Electronic Reporting****660.500: Cigarette Nicotine Yield Reporting Form****660.600: Severability****660.001: Purpose**

The purpose of these regulations is to implement M.G.L. Chapter 94, section 307B, which mandates reporting of certain information relating to nicotine yield of tobacco products to the Department of Public Health.

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amount of free nicotine, the total nicotine content of the tobacco and other design features of the cigarette.

Commissioner means the Commissioner of the Department of Public Health.

Department means the Department of Public Health.

Federal Trade Commission means the United States Federal Trade Commission.

Manufacturer means any person or entity, including any repacker or relabeler, manufacturing, fabricating, assembling, processing, or labeling a finished cigarette or smokeless tobacco product. The term does not include any person or entity only distributing finished cigarettes or smokeless tobacco products.

Smokeless Tobacco means any cut, ground, powdered, or leaf tobacco that contains or delivers nicotine and that is intended to be placed in the oral cavity without burning.

Smokeless Tobacco Nicotine Yield Rating means a composite of information intended to predict the range of nicotine that each smokeless tobacco product can be expected to provide to the average consumer based upon the amount of nicotine in the tobacco, the pH of the tobacco, the amount of unionized (free) nicotine in the product and other design features.

660.100: General Requirements for Annual Reports by Manufacturers

(A) On or before December 1, 2004, and by every December 1 thereafter, the manufacturer of any cigarette sold in the Commonwealth shall report to the Department, in accordance with these regulations, certain characteristics of cigarettes (105 CMR 660.101) and smokeless tobacco products (105 CMR 660.106) related to nicotine yield. On or before December 1, 2005 and by every December 1 thereafter, the manufacturer of cigarettes sold in the Commonwealth shall report to the Department, in accordance with these regulations, additional information concerning nicotine yield for selected brands (105 CMR 660.102 and 660.103). Reports shall be

submitted electronically to the Department, in accordance with the technical specifications of the Department described in 105 CMR 660.400. All raw data generated by testing in accordance with these regulations shall be submitted as part of this electronic report. The manufacturer shall also provide the name, job title, address, and telephone number of the individual designated by the manufacturer as the Department's contact person concerning 105 CMR 660.000.

(B) Nothing in this section shall prohibit a manufacturer or distributor of cigarettes or smokeless tobacco products from selling such products to an in-state merchant for sale or distribution outside of the Commonwealth.

660.101: Cigarette Nicotine Yield Reporting Requirements: Product Design Characteristics

For each brand of cigarette sold in the Commonwealth, manufacturers shall provide to the Department on or before December 1, 2004, and by every December 1 thereafter, the following information about the product and its design characteristics, as described and defined in section 660.200 (B). Such information shall be used for the selection of a sample of brands to be tested for nicotine yield under section 660.102, and to develop a multiplier to predict the nicotine yield for brands not tested for nicotine yield under 660.103. Testing shall be done according to testing conditions specified in 105 CMR 660.200 (B). The cigarette characterization data shall be reported to the Department on the form attached to these regulations as 105 CMR 660.300.

(A) Market Category

- (1) Market Share (U.S. %) (for the prior calendar year)
- (2) Menthol/ Non-Menthol
- (3) Packaging (e.g. hard pack, soft pack, tin)
- (4) Price Tier (e.g. premium, branded generic, generic)



(H) Tobacco Analysis

- (1) Moisture (conditioned, %)
- (2) Nicotine Content (mg/ cig)

(I) Smoking Analysis

- (1) FTC Nicotine Yield (mg) (most recent)
- (2) FTC Tar Yield (mg) (most recent)
- (3) FTC CO Yield (mg)
- (4) FTC Puff Count
- (5) Filter Efficiency (nicotine, %)

(J) Physical Properties

- (1) Linear Burn Rate (mm/min)
- (2) Mass Burn Rate (mg/min)

660.102: Additional Cigarette Nicotine Yield Reporting Requirements: Selection and Testing of Brands

- (A) (1) In each annual report submitted in accordance with section 660.100, a manufacturer shall include, as part of the nicotine yield report, the information specified in sections 660.102 (B) and 660.104 for each brand selected by the Department under CMR 660.102 (A) (3). For purposes of section 660.102, the term "brand family" shall mean a number of different, though highly similar cigarette products marketed under one general name; e.g. regular, longer-length and cigarettes of the same brand.
- (2) On or before December 1, 2005, and by every December 1 thereafter, the manufacturer of any cigarette product sold in the Commonwealth shall provide to the Department nicotine yield testing results for selected brands. The Department will select by February 1, 2005, and

by every February 1 thereafter, brands for testing in accordance with the requirements of subsection 660.102 (A) (3).

(3) All manufacturers shall test for nicotine yield, in accordance with section 660.102(B), the lesser of 15 cigarette brands or the number of cigarette brands the manufacturer offers for sale in the Commonwealth. Manufacturers whose total U.S. market share exceeds one percent (1%) shall test an additional number of selected brands based on the following table.

% Share of U.S. Market	Number of Additional Brands Tested
1-5	10
5-15	15
15-25	25
25+	50

(B) Manufacturers shall test all brands selected pursuant to section 660.102 (A) for nicotine yield, in accordance with the Massachusetts testing conditions specified in section 660.200

(C). Testing and measurement for nicotine yield shall comply with the sampling and conditioning standards set forth in 105 CMR 660.200 (A). The cigarette nicotine yield shall be reported to the Department in accordance with the form attached to these regulations as 105 CMR 660.301.

#### 660.103 Nicotine Yield Testing of All Other Cigarette Brands

For brand families not subject to the requirements of 105 CMR 660.102 (A), nicotine yield levels shall be determined by multiplying by a numerical factor approved by the Department which is intended to approximate the ratings for nicotine delivery under average smoking conditions derived by tests conducted in preceding years. The cigarette nicotine yield ratings shall be reported to the Department on the form attached to these regulations as 105 CMR 660.301.



660.104 Testing of Free Nicotine

On or before December 1, 2006 and by every December 1 thereafter, for each brand of cigarette selected for testing and reporting pursuant to section 660.102 (A), the manufacturer shall provide to the Department the percent of free (unionized) nicotine in the smoke when tested under the Massachusetts condition specified in section 660.200 (C). Manufacturers shall use the testing method specified in section 105 CMR 660.200 (D), and percent of free nicotine shall be reported to the Department in accordance with the form attached to these regulations as 105 CMR 660.301.

660.105 Testing of Human Nicotine Intake

Any brand offered for sale for the first time in the Massachusetts market after January 1, 2005 may be selected by the Department for testing of human nicotine intake, as determined in accordance with 105 CMR 660.200 (E), and reported on the form attached to these regulations as 105 CMR 660.302. The report shall be filed within six months of placing the product on the market in Massachusetts.

*how to be determined, agree on standard!*

660.106: Smokeless Tobacco Products: Nicotine Yield Reporting Requirements

Smokeless tobacco product manufacturers shall include in their annual report a rating for nicotine yield for each brand sold in the Commonwealth, which shall include:

*24 hr. urine  
NEs  
variability  
topography*

- (A) pH of tobacco;
- (B) moisture content as a percent of weight of tobacco;
- (C) nicotine in milligrams per gram of tobacco;
- (D) nicotine as a percent of dry weight of tobacco;
- (E) percent of unionized (free) nicotine; and
- (F) total unionized (free) nicotine in milligrams per gram of tobacco.

Testing shall be done according to testing conditions specified in 660.200 (A) and 660.200 (B)

(1). The smokeless tobacco nicotine yield rating shall be reported to the Department as specified on the form attached to these regulations as 105 CMR 600. 303.

660.200: Testing Methods

(A) Sampling and Conditioning. Conditioning for testing of tobacco products shall be done in accordance with the International Organization for Standardization (ISO), 3402, third edition, 1991-07-01 entitled "*Tobacco and Tobacco Products -- Atmosphere for Conditioning and Testing*". Cigarettes shall be sampled using international standard ISO §243:98 (E) entitled "*Cigarette – Sampling*". At a minimum, for each brand sampled, 35 packages of cigarettes shall be purchased from a Massachusetts wholesaler at a single point in time. Ten of these packs shall be mailed or delivered to the Department of Public Health. Smokeless tobacco products will follow the sampling protocol outlined in 660.200 (B) (1).

(B) Nicotine Yield: Product Design Characteristic Testing

(1) Nicotine content and moisture content in cigarettes and smokeless tobacco products, and pH in smokeless tobacco products shall be measured in accordance with the guidelines entitled "*Requirements for Annual Submission of the Quantity of Nicotine Contained in Smokeless Tobacco Products Manufactured, Imported, or Packaged in the United States*," most recently published in the Federal Register on March 23, 1999 (Volume 64, Number 55), or comparable method approved by the Department.

(2) Percent filter ventilation means the level of air dilution in the whole smoke, described in percent. This shall be measured in accordance with ISO standard 9512, or comparable method approved by the Department.

(3) Paper porosity shall be determined based on the CORESTA standard (where a CORESTA unit is the flow of air in  $\text{cm}^3$  per minute passing through a  $1 \text{ cm}^2$  surface of a test apparatus at a measuring pressure of 1.00 kPa), or comparable standard approved by the Department.

(4) Pressure drop is defined as the pressure required to force air through the full length of a cigarette at the rate of 17.5 ml/sec (20 °C, 760 torr). This value is expressed as inches of water, and shall be determined in accordance with ISO 6565: 1999 or comparable method approved by the Department.

(5) Filter efficiency of nicotine is the amount of smoke nicotine that is retained on a filter plug under standard FTC smoking conditions expressed as a percentage of the total amount of smoke nicotine presented to the filter. This will be determined as the amount of nicotine contained in the cigarette minus the FTC nicotine yield, divided by the amount of nicotine contained in the cigarette.

(6) Linear burn rate (or static burn rate) shall be the elapsed time taken for a measured length (40 mm) of a cigarette to burn by free combustion, expressed in mm/min. Mass burn rate shall be calculated by multiplying the linear burn rate by the tobacco column weight (mg) per unit length (mm), and will be expressed in mg/min.

(7) Moisture of tobacco shall be determined in accordance with ASAE S487 DEC97 ("Moisture Measurement- Tobacco") or comparable method approved by the Department.

(8) Percent Filter Tip Ventilation means the level of air dilution in the whole smoke, as provided by the perforations made in the cigarette filter tip, described in percent. This shall be measured using the Filter Dilution (Ventilation) Testing Instrument (FDT) from Fidus Instrument Corporation, product no. FDT 232; or FIAL Tip and Envelope

Ventilation/Pressure Drop QTM5U machine or equal approved by the Department, and shall be used in accordance with manufacturer instructions. Two cigarettes shall be randomly selected from each sampled pack, conditioned, and tested for percent filter ventilation. The average percent filter ventilation shall be computed for the 100 cigarettes tested.

(C) Modified FTC Testing Method.

- (1) Nicotine delivery under average smoking conditions for all cigarettes selected pursuant to section 660.102 (A) shall be evaluated using the Cambridge Method, which has been approved by the Federal Trade Commission (FTC) as the standard for nicotine testing since 1966, and adopted for international purposes by the ISO. See Federal Register, Vol. 32, No. 147, page 11178, dated August 1, 1967, as modified by the FTC in Federal Register, Vol. 45 No. 134, pages 46483-46487, dated July 10, 1980; ISO 10315, 91-08-01 entitled "Cigarettes-Determination of Nicotine in Smoke Condensates-Gas-Chromatographic Method"; ISO 3308, third edition, 1991-10-15, "Routine Analytical Cigarette-Smoking Machine - Definition of Standard Conditions"; and ISO 7201, second edition, 1997-01-15, "Routine Analytical Smoking Machine Additional Test Methods". Two cigarettes shall be randomly selected from each pack for a sample of 50 cigarettes.
- (2) The Department has modified the FTC and ISO conditions to require the following changes to the testing method:
  - (a) Puff volume as prescribed in the FTC method and in the ISO 3308: 4.3 shall be increased from 35 ml to 45 ml;
  - (b) Puff frequency as prescribed in the FTC method and ISO 3308: 4.4 shall be changed from one puff each minute to one puff every 30 seconds;

(c) Puff duration shall remain at two seconds;

(d) 50% of the ventilation holes must be blocked by placing a strip of mylar adhesive tape, Scotch Brand product no. 600 Transparent Tape (Acetate) or other method approved by the Department. The tape shall be cut so that it covers 50% of the circumference and is tightly secured from the end of the filter to the tipping overwrap seam;

(e) Number of cigarettes smoked per port shall be three, provided that the limit of 150 milligrams of tar is not exceeded (see ISO 4387).

(D) Free Nicotine Testing Method Free nicotine shall be tested in accordance with the method described in Pankow, J.F., Tavakoli, A.D., Luo, W., Isabelle, L.M. "Percent Free-Base Nicotine in the Tobacco Smoke Particulate Matter of Selected Commercial and Reference Cigarettes", Chem. Res. Toxicol., pp , 2003 or a comparable method approved by the Department.

(E) Human Intake Testing Method. Sixty smokers (30 male, 30 female) shall be selected for each brand to be tested pursuant to section 660.105. They shall have smoked for at least five years, currently smoke at least 15 cigarettes per day, and have smoked a brand with equivalent levels of tar and nicotine for at least three months immediately prior to testing. This set of smokers shall be tested for nicotine intake for each new brand by collecting a 24-hour urinary excretion sample and testing for levels of nicotine and its metabolite, cotinine, using gas chromatography-mass spectrometry, as described in Jacob P 3rd, Benowitz NL, Shulgin AT, "Recent Studies of Nicotine Metabolism in Humans," Pharmacology and Biochemical Behavior 1988; 30(1):249-53, or comparable method approved by the Department. Research on human

intake of nicotine shall be conducted in accordance with federal regulations governing protection of human subjects, Title 45 of the Code of Federal Regulations, Part 46.

**660,300: Cigarette Nicotine Yield Reporting Form: Product Design Characteristics**  
**Due December 1, 2004 and every December 1 thereafter**

Brand	Sub-Brand	Market Share (U.S., %)	Menthol/Non-Menthol	Packaging	Price Tier	Total Length (mm)	Filter Length (mm)	Circumference (mm)

Brand	Sub-Brand	Total Weight (g)	Tobacco Weight (g)	Tobacco Density (mg/cc)	Filter Type	Ventilation Rate (%)	Perforation	# Rows	# Holes/Row

Brand	Sub-Brand	Pressure Drop Open (inches)	Pressure Drop Sealed (inches)	Pressure Drop Filter (inches)	Pressure Drop Tobacco (inches)	Paper Permeability (coresta)	Method of Permeation

Brand	Sub-Brand	Moisture (conditioned, %)	Nicotine Content (mg/cig)		FTC Nicotine (mg)	FTC Tar (mg)	FTC CO (mg)

Brand	Sub-Brand	FTC Puff Count	Filter Efficiency (nic, %)	Linear Burn Rate (mm/min)	Mass Burn Rate

N.B.: The electronic form may be one spreadsheet consisting of the fields described above listed as a single row header. They are broken up here for display.

660.301: Nicotine Yield Reporting Form: Cigarettes

Due December 1, 2005 and every December 1 thereafter.

Brand	Sub Brand	Nicotine Yield (mg (MA test results))	Multiplier (if used)	Puff Count	% Free Nicotine

660.302 Nicotine Intake Reporting Form (for new brand families only)

Brand	Sub Brand	Nicotine Intake (ng/L)	Std Dev	C.V.	Cotinine (ng/L)	Std Dev	C.V.



**660.303 Nicotine Yield Reporting Form: Smokeless Tobacco**  
Due December 1, 2004

Brand	Sub-Brand	Moisture Content (%)	Nicotine (% Dry Weight)	Nicotine (mg/g)	pH	Total Unionized (free) Nicotine

**660.400: Electronic Reporting**

All manufacturers submitting a report in accordance with 105 CMR 660.000 shall adhere to the following technical specifications:

- (1) Reports shall be submitted in electronic (and not paper) format.
- (2) Data shall be submitted within a spreadsheet, Microsoft Excel or compatible program approved by the Department, using the format displayed in sections 660.300 through 660.303. A single, separate file or worksheet shall be used for each form submission.
- (3) The Department will provide electronic templates for use in reporting at the request of the manufacturer.
- (4) All raw data generated by testing in accordance with these regulations shall be submitted as a separate part of the electronic report. The raw data includes each measurement taken to achieve any reported average or figure.

660.200: Severability

If any provisions of 105 CMR 660.000 are held invalid for any reason whatsoever, such declaration shall not effect any other portion of 105 CMR 660.000, which shall remain in full force and effect, and to this end, the provisions of 105 CMR 660.000 et seq. are hereby declared severable.

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